

COMMUNITY HEALTH WORKER

Lupus Clinical Trials
Training Program

LuCTT



FACILITATOR'S GUIDE



AMERICAN COLLEGE
of RHEUMATOLOGY
Empowering Rheumatology Professionals



lupusinitiative.org/LUCTT



LuCTT

The American College of Rheumatology developed the *Community Health Worker (CHW) Lupus Clinical Trials Training (LuCTT) Program Facilitator's Guide* in collaboration with KDH Research & Communication and subject matter experts.

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BACKGROUND

Lupus is a chronic disease that disproportionately affects minorities, including African American and Latino women. In the United States, the reported prevalence is one out of 15 people. Lupus, an autoimmune disorder, causes inflammation that affects the skin, joints, and multiple organ systems in the body. Lupus has no cure, but early diagnosis and treatment reduces organ damage and the physical, mental, and social effects of lupus; and decreases possible medical complications and risk of death.

Clinical trials systematically explore new and better treatments for lupus, but patients most affected by lupus are the least likely to participate in clinical trials. In fact, African Americans represent approximately 12 percent of the US population, but only five percent of clinical trial participants. Similarly, Latinos make up 16 percent of the US population but only one percent of clinical trial research participants. The Community Health Worker Lupus Clinical Trials Training (LuCTT) program exists to change these statistics.

WHAT IS LuCTT? WHAT DOES IT DO?

Thank you for your participation in the Community Health Worker **L**upus **C**linical **T**rials **T**raining (LuCTT) program. **LuCTT** is a program that is designed to support recruitment and enrollment of minority populations affected by lupus into clinical trials. LuCTT will consist of multiple interconnected toolkits for state, local, and community organizations to host regional Community Health Worker (CHW) training summits to prepare CHWs to support and increase lupus clinical trial recruitment and participation by increasing lupus clinical trial awareness and providing clinical trial and health system navigation. Ultimately, the LuCTT toolkits will work together in the real world to increase minority participation in lupus clinical trials.

The LuCTT program is made up of four inter-connected parts. These parts are:

The Summit Playbook.

The summit playbook will be used by lead organizations to implement LuCTT. It includes information on how to build partnerships, identify training facilitators, and host a LuCTT summit.

CHW Online Learning Modules.

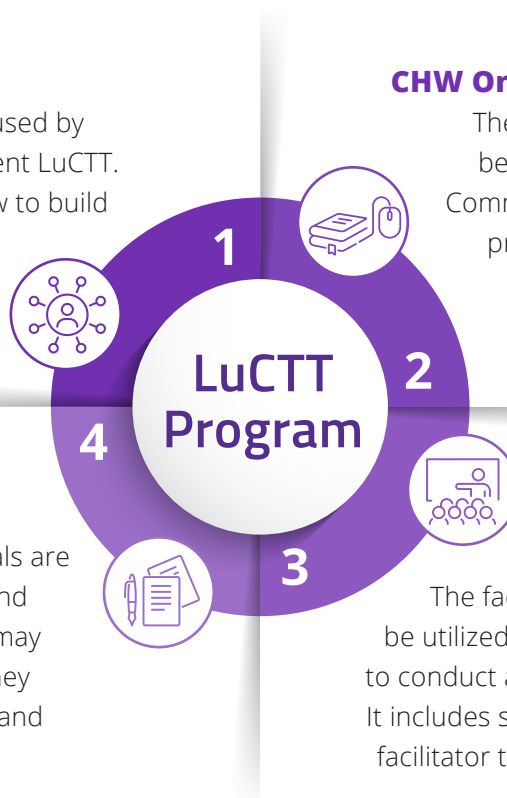
The online learning modules will be completed independently by Community Health Workers (CHW) prior to attending an in-person summit. CHWs will learn key content about lupus and clinical trials.

Patient Education Materials.

The patient education materials are distributed to CHWs who attend a LuCTT summit so that they may use them with their clients. They contain information on lupus and lupus clinical trials.

The Facilitator's Guide and In-Person Training Summit.

The facilitator's guide is designed to be utilized by a selected CHW facilitator to conduct an in-person training summit. It includes step-by-step instructions for a facilitator to lead in-person training with CHWs at the summit.



WHY LuCTT?

As a CHW trainer, you are in an ideal position to equip CHWs with the knowledge and skills to help spread awareness about lupus clinical trials. You are trusted members of your community, interacting with clients daily. Clinical trials are a potentially life-changing health service of which many people in your community may not be aware. You can educate and empower your clients to make informed decisions about participation in a clinical trial and if clinical trials are right for them. Clinical trials have the potential to benefit individuals working to improve their health and life with chronic illnesses. Clinical trials can also create knowledge, medicine, and tools to benefit future generations of people with lupus. Clinical trials will not be for everyone, but it is everybody's right to know the possible benefits of trials and to freely decide whether to participate.

The knowledge and skills gained by CHWs participating in LuCTT benefit them in all of their outreach and support activities. The knowledge gained from this program is generalizable to all clinical trials, not just lupus clinical trials, and as such, CHWs will develop an integral skillset that will help them with work in other areas. CHWs were chosen for this project because they are often members of the communities that they serve, which allows them to develop trusting one-on-one relationships with clients. CHWs can provide health systems navigation, interpretation and translation services, culturally appropriate health information and education, advocacy for patient and community health needs, and counseling and guidance on health behaviors.

HOW THE FACILITATOR'S GUIDE WORKS

LuCTT is structured into a two-part CHW training. The first part is an online course that CHWs will complete before the in-person summit. The online course will provide the CHWs with knowledge about lupus and of clinical trials. The second part is the in-person training summit during which CHWs will learn and practice the skills to conduct lupus clinical trials outreach with their clients.

The LuCTT facilitator's guide is a tool to for you to lead the in-person training summit. We provide an overview of the summit timeline below and a more detailed timeline in each session.

| Activity | Estimated Time |
|--|------------------------|
| Introduction | 20 minutes |
| Session One: Lupus and Clinical Trial Health Disparities | 40 minutes |
| Break | 10 minutes |
| Session Two: Lupus Clinical Trials Overview | 40 minutes |
| Break | 10 minutes |
| Session Three: Patient and Provider Barriers to Clinical Trial Participation | 65 minutes |
| Break | 30 minutes |
| Session Four: Communicating Lupus Clinical Trial Information and Navigating Between Providers and Clinical Trial staff | 40 minutes |
| Break | 10 minutes |
| Session Five: How to Conduct Outreach on Lupus Clinical Trials | 40 minutes |
| Conclusion | 10 minutes |
| Total time for Summit | 5 hours and 15 minutes |

SESSION MATERIALS

Successful implementation of the LuCTT sessions requires a few materials that implementing organizations must provide. These materials are listed for each session in the “Materials Needed” section.



- ✓ Pens
- ✓ Nametags
 - » CHWs should collect their nametags when they sign in at the beginning of the day
- ✓ Cups or bowls
 - » Enough to have one per group of CHWs
- ✓ Packets of summit documents
 - » CHWs should collect these when they sign in at the beginning of the day
 - » Self-assessment forms (2 for each CHW participating)
 - » Skills check sheet forms (8-12 for each CHW participating)
- ✓ Copy of trivia game (for the facilitator)
- ✓ Role play scenario handouts
- ✓ Videos
- ✓ Manila envelopes
 - » These will be used to store the self-assessment and skills check sheet forms the CHWs will complete



The sessions include videos, which can be accessed at www.thelupusinitiative.org/luctt



INTRODUCTION



Facilitator overview

This session will introduce CHWs to the LuCTT program, its goals and objectives.



Session learning objectives

After completing the session, CHWs will be able to:

- ✓ Discuss what LuCTT is and what they will learn
- ✓ Explain how education and outreach fits into their existing CHW role



Materials needed

- ✓ None



Session Agenda

| Activity | Time |
|-----------------------------|------------|
| Welcome and introductions | 10 minutes |
| Guidelines | 10 minutes |
| Total Time for Introduction | 20 minutes |



Introduction session content



Hello, my name is _____. Welcome to the first session of the Lupus Clinical Trials Training (LuCTT – loo sit) program.

The goal of LuCTT is to prepare you to conduct outreach and education on lupus clinical trials with African Americans and Latinos and in particular women to increase minority involvement in lupus clinical trials. You will learn information and skills to teach clients about lupus, clinical trials, and how participating in lupus clinical trials is beneficial.



Provide CHWs with the following information about yourself:

- » Where you work and your role there
- » Your education and your experience
- » Why you are interested in helping African Americans and Latinos learn about lupus and clinical trials



Before we go any further, let's discuss some guidelines for the summit to help us support each other and learn.



Read each of the guidelines listed below aloud and provide a brief explanation if there are any questions.

LuCTT Ground Rules for Learning Together:

- » Begin and end on time
- » Participate actively
- » Ask questions
- » Allow everyone a chance to speak
- » Take breaks when you need them
- » Have fun!



There will be five sessions included in today's summit, each lasting approximately 45 minutes to an hour. We will also have short breaks between sessions and a longer 30-minute lunch break. In session one, we will cover an overview of lupus and clinical trial health disparities. In session two, we will discuss lupus clinical trials. In session three, we will discuss barriers to clinical trial participation. In session four, we will learn strategies to communicate lupus clinical trial information and how to navigate between providers and clinical trial site staff. Lastly, in session five, we will cover how to conduct outreach on lupus clinical trials with your clients.

The format of each session will be similar. We will break into groups, then we will briefly review the corresponding online learning modules that you all completed. Next, we will watch a video that illustrates scenarios that you might encounter while conducting lupus outreach. After watching each video, you will discuss the video. Then, each group will complete an activity to practice the skills.

We have some volunteers to help with the summit today. They will assist me in handing out papers, collecting skills check sheets and self-assessments, and making sure that everything runs smoothly.



Allow the volunteers a few minutes to introduce themselves to the CHWs.

SESSION ONE: LUPUS AND CLINICAL TRIAL HEALTH DISPARITIES



Facilitator overview

Session one will develop CHWs' skills and self-efficacy to explain lupus clinical trials and the importance of increasing minority representation in lupus clinical trials. CHWs will learn about the health disparities between minority patients with lupus, the low participation of minority patients in clinical trials, and how clinical trial participation can reduce lupus health disparities.



Session learning objectives

After completing the session, CHWs will be able to:

- ✓ Teach clients about lupus health disparities among minorities
- ✓ Explain how clinical trial participation can reduce lupus health disparities



Materials needed

You will need the following materials for this session:

- ✓ Pens
- ✓ Trivia game
- ✓ Self-assessment sheets
 - » One per CHW
- ✓ Manila envelope



Session Agenda

| Activity | Time |
|----------------------------|------------|
| Review of key points | 5 minutes |
| Self-assessment form | 5 minutes |
| Video one and discussion | 10 minutes |
| Group introductions | 5 minutes |
| Trivia game | 15 minutes |
| Total Time for Session one | 40 minutes |



Session one content



Welcome to LuCTT session one. During this session, we will learn about health disparities that minority women with lupus face and how clinical trial participation can help reduce those disparities.

First, I want to review several key points from the online learning module that corresponds to this session:

- » Lupus is more frequent among African American and Latina women
- » African Americans and Latinos experience more severe lupus effects
- » African Americans and Latinos are underrepresented in clinical trials.



Ask CHWs to take out a self-assessment form from their packets of summit documents.



Now, you are going to complete a self-assessment where you will rate your skills and ability to perform the behavior listed on the sheet. You will complete the self-assessment twice during the summit – now at the beginning of the summit before we practice our skills and then at the end of the summit, after we practice our skills. These sheets will help us understand the effectiveness of the LuCTT program.

Do NOT put your full name on any of the sheets in your packet. Instead, you should put your initials, the last three letters of your last name, and your state at the top of the sheets. For example, if your name is Maritza Ana Perez and you live in Georgia, put MAP PER GA.



Allow the CHWs a few minutes to complete the self-assessment form. Ask volunteers to collect the completed self-assessment forms.

Have the CHWs divide into groups of four or five. Explain to the CHWs that they will remain in these groups for the remainder of the summit to complete discussions, activities, and role play scenarios.



Before we watch video one, let's get to know our groups a little better. Take a few minutes to introduce yourself, share your personal learning goals, and what you hope to accomplish by completing the LuCTT program.



Allow the groups a total of 5 minutes to complete introductions.

Explain to the CHWs that video one is about a CHW discussing lupus and clinical trial health disparities and the importance of clinical trials with a patient. Show them video one.



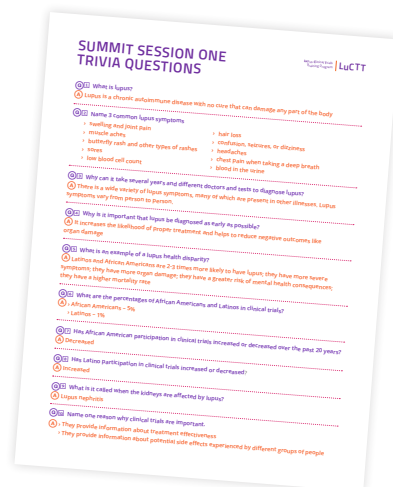
Now, in your groups discuss what things the characters in the video did well and what things you would do differently. Do you think that the CHW handled the situation appropriately?



Give groups several minutes to discuss the video.



Now, let's complete our first activity - a trivia game. I will ask a question about lupus or clinical trials and each group will write their answer on the sheet of paper. After I finish reading the questions, I announce the correct answers. Each team will score their sheet and raise their hand to indicate if their team got the question right. Please come up with a team name and write it down on your piece of paper.



Complete the first activity – the trivia game, using the provided question and answer sheet. This should take approximately 15 minutes.



SESSION TWO: LUPUS CLINICAL TRIALS OVERVIEW



Facilitator overview

Session two will improve CHWs' knowledge, skills, and self-efficacy to teach patients about clinical trials, how they work, and what to expect from participating in a trial.



Session learning objectives

After completing the session, CHWs will be able to:

- ✓ Describe to clients what a clinical trial is and what they can expect during participation
- ✓ Explain to someone how to identify rheumatologists near their geographic area
- ✓ Describe the different phases of clinical trials to clients
- ✓ Teach patients different strategies to learn about clinical trials



Materials needed

You will need the following materials for this session:

- ✓ Pens
- ✓ A cup or bowl for each group
- ✓ Video two
- ✓ Role play two handout
- ✓ Skills check sheets (two to three per CHW)
- ✓ Manila envelope



Session Agenda

| Activity | Time |
|------------------------------|------------|
| Review of key points | 5 minutes |
| Video two and discussion | 10 minutes |
| Role play two and discussion | 25minutes |
| Total Time for Session two | 40 minutes |



Session two content



Welcome to LuCTT session two. During this session, we will learn about lupus clinical trials and teach you strategies to share with patients to learn more clinical trials and the pros and cons of participating.

First, I want to review several key points from the online learning module that corresponds to this session:

- » A clinical trial is a research study involving people to find new treatments and medicine for conditions, like lupus
- » The three different phases of clinical trials:
 - › Phase I is to help establish safe doses and possible side effects in healthy patients
 - › Phase II is to check whether the new drug works and to evaluate it for safety in people with the condition
 - › Phase III is to evaluate if the new treatment is better than the care that is currently available
- » You can direct patients can use different resources to learn about clinical trials, such as online resources and their healthcare providers.



Explain to the CHWs that video two contains is about a CHW explaining the basics of lupus clinical trials to a patient and showing them how to find a clinical trial that matches their needs. Show them video two.



Now, in your groups discuss what things the characters in the video did well and what things you would do differently. Do you think that the CHW handled the situation appropriately? How would you react in a similar situation? Do you think you be able to discuss sensitive topics with your clients?



Give groups several minutes to discuss the video.



Great discussion everyone. Now, let's move on to the activity for this session, which are role play scenarios. For all of the role plays, each person in your group will get the opportunity to play the role of the CHW conducting outreach once. A different person in your group will play the person with lupus. The other members of the group will use skills check sheets to assess the person role playing as the CHW. Then, you'll switch and a new person in your group will role play as the CHW.



Explain that the role plays are organized around four general personality types that a CHW might encounter when conducting outreach. Those personalities are argumentative, positive, nervous, and indifferent.



Each group has a bowl or cup on your table with a few slips of paper in it. These slips of paper have the four different personalities on them. Before we begin the role play, you will pick one piece of paper from the bowl. Then, when it's your turn to play the client, you will role play that personality. After you have all selected your personalities, put the paper back in the bowl or cup.



Instruct each group to draw their personality pieces of paper.



Select a person who will role play the CHW conducting outreach first and then the CHW who will role play the client with lupus. The other members of the group will use skills check sheets to assess the person acting as the CHW. When it's your turn to role play the CHW, please hand out copies of your skills check sheets with your initials on them to the group members who are assessing your skills.

The role play scenario for this session is a CHW talking with a client who just received information on clinical trials from her provider and wonders about the risks and benefits



Instruct CHWs to complete role play two with each of the CHWs role playing as the CHW once. This should take approximately 20 minutes. Remind CHWs to complete their skills check sheets as each CHW is role playing.

Ask volunteers to collect all skills check sheets from each group and place them in manila envelopes.



Now as a group, talk about the different situations and effective ways to approach sensitive topics or difficult conversations with your clients. I will walk among the different groups to help guide the discussions.



Walk among the groups as they discuss the role plays.



We are now going to have a short 10-minute break if you need to use the restroom or stretch. Please return on time.



BREAK – TIME: 10 MINUTES

SESSION THREE: PATIENT AND PROVIDER BARRIERS TO CLINICAL TRIAL PARTICIPATION



Facilitator overview

This session provides CHWs with the skills and self-efficacy to help minority patients overcome barriers to clinical trial participation. CHWs will engage in a variety of learning opportunities to develop skills to support patients to participate in clinical trials.



Session learning objectives

After completing the session, CHWs will be able to:

- ✓ Explain to patients how to overcome the various obstacles to participating in a clinical trial



Materials needed

You will need the following materials for this session:

- ✓ Pens
- ✓ Video three
- ✓ Role play three handouts
- ✓ Cup or bowl
- ✓ Skills check sheets (four to six per CHW)
- ✓ Manila envelope



Session Agenda

| Activity | Time |
|----------------------------------|------------|
| Review of key points | 5 minutes |
| Video three and discussion | 10 minutes |
| Role play three A and discussion | 25minutes |
| Role play three B and discussion | 25 minutes |
| Total Time for Session three | 65 minutes |



Session three content



Welcome to session three of LuCTT. During this session, we will review how to teach patients about the best way to overcome obstacles to participating in lupus clinical trials.

First, I want to review several key points from the online learning module that corresponds to this session:

- » Patients may face barriers to participating in a clinical trial
- » Most barriers can fall into three categories: access barriers, knowledge barriers, and opportunity barriers



Explain to CHWs that video three is about a CHW having a conversation with a client about barriers they face to clinical trial participation. Show them video three.



Now, in your groups discuss what things characters in the video did well and what things you would do differently. How would you react in a similar situation? Do you think you will be able to discuss solutions to barriers with your clients?



Give groups several minutes to discuss the video.



Great discussion everyone. Now let's move on to the first role play scenario for session three. Session three will be a little bit different than the first two because we are going to have two separate role play scenarios.



Instruct each group to draw their role play personality for role play three-a.



Select a person who will play the person with lupus and a different person to role play the CHW conducting outreach. The other members of the group will use skills check sheets to assess the person acting as the CHW. When it's your turn to role play the CHW, please hand out copies of your skills check sheets with your initials on them to the group members who are assessing your skills.

The first role play scenario for this session is a CHW explaining clinical trial support to a client.



Instruct CHWs to complete role play three A with each of the CHWs role playing as the CHW once. This should take approximately 20 minutes. Remind CHWs to complete their skills check sheets as each CHW is role playing.

Ask volunteers to collect all skills check sheets from each group and place them in manila envelopes.



Now as a group, talk about the different situations and effective ways to approach conversations about barriers with your clients. I will walk among the different groups to help guide the discussions.



Walk among the groups as they discuss the role plays.



The second role play scenario for this session is a CHW meeting with a clinical trial Principal Investigator (PI) to discuss the specific barriers in their area.



Instruct each group to draw their role play personality for role play three B.



Select a person who will play the clinical trial PI and a different person to role play the CHW conducting outreach. The other members of the group will use skills check sheets to assess the person acting as the CHW. When it's your turn to role play the CHW, please hand out copies of your skills check sheets with your initials on them to the group members who are assessing your skills.



Instruct CHWs to complete role play three B. This should take approximately 20 minutes. Remind CHWs to complete their skills check sheets as each CHW is role playing.

Ask volunteers to collect all skills check sheets from each group and place them in manila envelopes.



Now as a group, talk about the different situations and effective ways to approach conversations about barriers with your clients. I will walk among the different groups to help guide the discussions.



Walk among the groups as they discuss the role plays.



We are now going to have a 30-minute lunch break. Please return on time.



BREAK – TIME: 30 MINUTES

SESSION FOUR: COMMUNICATING LUPUS CLINICAL TRIAL INFORMATION AND NAVIGATING BETWEEN PROVIDERS AND CLINICAL TRIAL STAFF



Facilitator overview

This session will develop CHWs' skills and self-efficacy for relaying information relating to lupus clinical trials, eligibility, and how to navigate between providers and clinical trial staff.



Session learning objectives

After completing the session, CHWs will be able to:

- ✓ Inform clients about clinical trial protocols, including randomization, health insurance costs, and informed consent
- ✓ Explain eligibility criteria for clients
- ✓ Teach clients how to navigate between providers and clinical trial site staff



Materials needed

You will need the following materials for this session:

- ✓ Pens
- ✓ Video four
- ✓ Role play four handout
- ✓ Cup or bowl
- ✓ Skills check sheets (two to three per CHW)
- ✓ Manila envelope



Session Agenda

| Activity | Time |
|-------------------------------|------------|
| Review of key points | 5 minutes |
| Video four and discussion | 10 minutes |
| Role play four and discussion | 25 minutes |
| Total Time for Session four | 40 minutes |



Session four content



Welcome to session four of LuCTT. During this session, we will learn how to teach clients how to navigate between their healthcare providers and clinical trial staff.

I want to review several key points from the online learning module that corresponds to this session:

- › Insurance companies can't deny people participating in an approved clinical trial, but sometimes there are extra costs that will depend on a person's insurance. They should call their insurance to find out what would be covered
- › Informed consent is a continuous process that consists of a document (consent form) and a series of conversations between the participant and clinical trial staff. Even after providing informed consent, a patient can withdraw from the trial at any time.



Explain to CHWs that video four is about a CHW explaining more detailed information about a clinical trial including randomization, effects on health insurance, eligibility criteria, and informed consent. Show them video four.



Now, in your groups discuss what things characters in the video did well and what things you would do differently. How would you react in a similar situation? Will you be able to communicate lupus clinical trial information to your clients?



Give groups several minutes to discuss the video.



Now we will complete the role play scenario for session four.



Instruct each group to draw their role play personality.



Select a person to play the person with lupus and another to role play the CHW conducting outreach. The other members of the group will use skills check sheets to assess the person acting as the CHW. When it's your turn to role play the CHW, please hand out copies of your skills check sheets with your initials on them to the group members who are assessing your skills.

The role play scenario for this session is a CHW helping a client fill out paperwork for clinical trial enrollment.



Instruct CHWs to complete role play four with each of the CHWs role playing as the CHW once. This should take approximately 20 minutes. Remind CHWs to complete their skills check sheets as each CHW is role playing.

Ask volunteers to collect all skills check sheets from each group and place them in manila envelopes.



Now as a group, talk about the different situations and effective ways to approaches to communicating lupus clinical trial information to patients and navigating between providers and clinical trial staff. I will walk among the different groups to help guide the discussions.



Walk among the groups as they discuss the role plays.



We are now going to have a short 10-minute break if you need to use the restroom or stretch. Please return on time.



BREAK – TIME: 10 MINUTES



SESSION FIVE: HOW TO CONDUCT OUTREACH ON LUPUS CLINICAL TRIALS



Facilitator overview

This session will give CHWs the in-depth knowledge required to conduct outreach to their patients on lupus clinical trials. CHWs will learn about the best methods for them to use to reach the greatest number of people, incorporating their outreach into ongoing community activities – health fairs, one on one meetings, and patient navigation events..



Session learning objectives

After completing the session, CHWs will be able to:

- ✓ Identify the best way to incorporate lupus clinical trial outreach into their existing community outreach



Materials needed

You will need the following materials for this session:

- ✓ Pens
- ✓ Video five
- ✓ Elevator speech handout



Session Agenda

| Activity | Time |
|-----------------------------|------------|
| Review of key points | 5 minutes |
| Video five and discussion | 10 minutes |
| Elevator speech activity | 25 minutes |
| Total Time for Session five | 40 minutes |



Session five content



Welcome to session five of LuCTT, which is the final session of our summit. During this session, we will learn about the best ways to incorporate lupus clinical trial outreach into your existing community outreach. It is important to remember that each organization that uses CHWs is unique and might have different needs to consider when incorporating lupus clinical trial outreach. It is possible that what will work for one organization may not necessarily work for another.



Explain to CHWs that video five is about a CHW demonstrating methods to weave clinical trial outreach into ongoing activities. Show them video five.



Now, in your groups discuss what things characters in the video did well and what things you would do differently. How would you react in a similar situation? How would you introduce the topic of lupus clinical trials with a client who doesn't have lupus?



Give groups several minutes to discuss the video.



We are now going to complete a different activity for session five. Each group is going to create one elevator speech that you could use for clinical trial outreach that they will present to the whole summit. You have a sheet indicating some of the things that you should include in your speech.



Give groups 15 minutes to draft their elevator speeches.



Each group will have two minutes to present their elevator speech to the summit. I will call up each group one at a time.



Allow each group to present their elevator speech to the rest of the summit.



Thank you for these great elevator speeches.

BONUS ACTIVITY (time permitting) **TIME: 25 MINUTES**



We have time to do one bonus activity which will allow us to practice our outreach skills with potential clients. This activity is like Four Corners, except we will use three corners – one each to represent the most common areas where we conduct outreach. So, one for home visits, one for health fairs, and one for clinic visits.



Instruct CHWs to go to the three corners. Try to ensure that the numbers are approximately even. Then, ask each group to count off by twos.



If you are a one, you will be role playing a CHW conducting outreach at one of the three areas. If you are a two, you will be role playing a client and you can pick one of the four different personas to play: argumentative, positive, nervous, and indifferent. Keep this persona in mind as you interact with the CHW who will be speaking with you. For the CHWs, you will need to adjust how you speak with the client based on the persona they have chosen to play.



Give CHWs 10 minutes to role play and then have the CHWs swap roles so that the CHWs role playing a client can now role play a CHW and vice versa. Allow CHW to role play for another 10 minutes.

CONCLUSION



Facilitator overview

This session will wrap up the LuCTT summit. If you have time, complete the bonus activity before this conclusion session.



Materials needed

- ✓ Self-assessment sheet (1 per CHW)
- ✓ Pens
- ✓ Manila envelope



Session Agenda

| Activity | Time |
|---------------------------|------------|
| Self-assessment sheets | 5 minutes |
| Goodbye statement | 5 minutes |
| Total Time for Conclusion | 10 minutes |



Conclusion session content



As I mentioned at the beginning of the summit, we need you to fill out two self-assessments. Take a few minutes to complete the second self-assessment keeping in mind all the skills that you have learned throughout the summit today.



Give CHWs a few minutes to complete their self-assessments and have your volunteers collect the self-assessments from each group and place them in a manila envelope.



You have all done a great job working on your skills to discuss this information about lupus clinical trials. Please join me in applauding each other for a job that has been fun, hard, and well-done. African American and Latino clients can definitely count on you to help educate them about lupus clinical trials in your communities! Remember to incorporate what you learned today into your existing outreach and utilize the patient materials in your packets to help facilitate conversations. You can also access the materials online at the URL on the bottom of the patient materials.



Dismiss CHWs from the summit.



FACILITATOR'S GUIDE SESSION MATERIALS

The following items accompany the facilitator's guide to help the summit run smoothly.

Summit Session one trivia questions

Roleplay scenario two

Roleplay scenario three-a

Roleplay scenario three-b

Role play scenario four

Elevator speech handout

SUMMIT SESSION ONE

TRIVIA QUESTIONS

Q1 What is lupus?

A Lupus is a chronic autoimmune disease with no cure that can damage any part of the body

Q2 Name 3 common lupus symptoms

- › swelling and joint pain
- › muscle aches
- › butterfly rash and other types of rashes
- › sores
- › low blood cell count
- › hair loss
- › confusion, seizures, or dizziness
- › headaches
- › chest pain when taking a deep breath
- › blood in the urine

Q3 Why can it take several years and different doctors and tests to diagnose lupus?

A There is a wide variety of lupus symptoms, many of which are present in other illnesses. Lupus symptoms vary from person to person.

Q4 Why is it important that lupus be diagnosed as early as possible?

A It increases the likelihood of proper treatment and helps to reduce negative outcomes like organ damage

Q5 What is an example of a lupus health disparity?

A Latinos and African Americans are 2-3 times more likely to have lupus; they have more severe symptoms; they have more organ damage; they have a greater risk of mental health consequences; they have a higher mortality rate

Q6 What are the percentages of African Americans and Latinos in clinical trials?

A › African Americans – 5%
› Latinos – 1%

Q7 Has African American participation in clinical trials increased or decreased over the past 20 years?

A Decreased

Q8 Has Latino participation in clinical trials increased or decreased?

A Increased

Q9 What is it called when the kidneys are affected by lupus?

A Lupus nephritis

Q10 Name one reason why clinical trials are important.

A › They provide information about treatment effectiveness
› They provide information about potential side effects experienced by different groups of people

ROLEPLAY TWO HANDOUT

SESSION 2:

CHW talks with a client
about risks and benefits
of clinical trials

A CHW is talking to one of her clients who has just had an appointment with her doctor. Client says the doctor talked to her about lupus clinical trials but didn't go into detail.

ARGUMENTATIVE

Instructions:



Read the Underlined text.



The *italicized* text are suggestions for continuing the conversation.

CHW



I want to expand a little bit about what your doctor talked about – some of the pros and cons of clinical trials.

Client



There's no way clinical trials could be beneficial to me. They are dangerous and could be harmful.

CHW



Respond to the client in the best way possible.

Client



Maintain an aggressive personality, constantly questioning and second guessing the CHW. You do not think that clinical trials are good for you.

CHW



Explain some of the pros and cons of clinical trials while trying to ease her misgivings.

Client



Some things you should say during the conversation:



The clinical trial researchers can't be trusted.



There's been racism in clinical trials before, so it could happen again.

CHW



Conclude the conversation

SESSION 2:

CHW talks with a client
about risks and benefits
of clinical trials

A CHW is talking to one of her clients who has just had an appointment with her doctor. Client says the doctor talked to her about lupus clinical trials but didn't go into detail.

POSITIVE

Instructions:



Read the Underlined text.



The *italicized* text are suggestions for continuing the conversation.

CHW



There's a lot to think about when considering whether to enroll in a clinical trial. I want to talk to you about some of the pros and cons.

Client



I'm not worried about any cons, I trust the people at the clinical trial to take care of me.

CHW



Respond to the client in the most appropriate way.

Client



You want to maintain a very positive personality. Even to the point of not being able to see any potential negative aspects of clinical trials.

CHW



Explain some of the pros and cons of clinical trials while making sure that the client is taking concerns seriously.

Client



Some things you should say during the conversation:



The chances of negative effects are very small, aren't they? I wouldn't need to worry about that.

Clinical trials seem like a great way to increase treatment for lupus. I don't think they seem that dangerous.

CHW



Conclude the conversation

SESSION 2:

CHW talks with a client
about risks and benefits
of clinical trials

A CHW is talking to one of her clients who has just had an appointment with her doctor. Client says the doctor talked to her about lupus clinical trials but didn't go into detail.

NERVOUS

Instructions:



Read the Underlined text.



The *italicized* text are suggestions for continuing the conversation.

CHW



I know you said your doctor had mentioned clinical trials at your last appointment.
I want to expand on some of the pros and cons that might have been mentioned.

Client



It sounds like there's potentially a lot of risk. That makes me really nervous about how I
would be affected.

CHW



How would you respond to this client?

Client



Anything that the CHW says to ease your concerns is not going to be successful. Continue to
be apprehensive and nervous about clinical trials.

CHW



Explain some of the pros and cons of clinical trials while trying to ease her fears.

Client



Some things you should say during the conversation:



I don't know if it's a good idea for me to do a clinical trial, it sounds really risky.

I'm afraid that I'll have negative reactions to the medicine.

I'm afraid of how the trial will disrupt my life.

CHW



Conclude the conversation

SESSION 2:

CHW talks with a client
about risks and benefits
of clinical trials

A CHW is talking to one of her clients who has just had an appointment with her doctor. Client says the doctor talked to her about lupus clinical trials but didn't go into detail.

INDIFFERENT

Instructions:



Read the Underlined text.



The *italicized* text are suggestions for continuing the conversation.

CHW



Your doctor has talked to you about clinical trials, right? I want to go over some of the pros and cons of participating so you can decide if it's right for you.

Client



I don't think clinical trials would be worth my time. There probably isn't any benefit for me.

CHW



How would you respond to this?

Client



You don't really care one way or the other. You're very apathetic about lupus clinical trials and can't be bothered to be interested in learning more about them.

CHW



Explain some of the pros and cons of clinical trials, always keeping in mind that it is their decision and you shouldn't pressure them.

Client



Some things you should say during the conversation:



I don't think there's enough benefit for me.

Why should I spend my time on something that might not even help me?

CHW



Conclude the conversation

ROLEPLAY THREE-A HANDOUT

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SESSION 3A:

CHW roleplays
explaining clinical trial
support to a client

A CHW is meeting with a client who is wondering about clinical trial support, how it works, whether she will receive any.

ARGUMENTATIVE

Instructions:



Read the Underlined text.



The *italicized* text are suggestions for continuing the conversation.

CHW



Sometimes clinical trials are able to offer support to the patients in them. This can include things like child support or transportation reimbursement.

Client



How can they expect me to participate in their trial if they won't give me any support? That won't work.

CHW



How would you respond to this?

Client



You should be very displeased that the trial might not offer you enough support. No matter what the CHW says, you are not convinced.

CHW



Explain the various resources that might be available for the client while making sure she has the facts.

Client



Some things you should say during the conversation:



If I'm not given enough support, then I won't participate in the trial.

How do I know that I'd really get support from them even if they say they're going to give it to me?

CHW



Conclude the conversation

SESSION 3A:

CHW roleplays explaining clinical trial support to a client

A CHW is meeting with a client who is wondering about clinical trial support, how it works, whether she will receive any.

POSITIVE

Instructions:



Read the Underlined text.



The *italicized* text are suggestions for continuing the conversation.

CHW



Clinical trials sometimes have the budget to offer the participants support with logistical issues like transportation costs.

Client



That's great! I know it would be a huge help if they could give me some money for child care or transportation.

CHW



How can you respond and educate?

Client



Maintain a positive personality. Even if the CHW says that you might not receive support from the clinical trial, you should talk about positive things.

CHW



Explain the various resources that might be available for the client while making sure she has the facts.

Client



Some things you should say during the conversation:



I think that the benefits of the trial would still outweigh any negatives, even if they can't give me any support.

I think it's great that they think about their patients like that! Even if they can't help as much as I would like, that's still good.

CHW



Conclude the conversation

SESSION 3A:

CHW roleplays explaining clinical trial support to a client

A CHW is meeting with a client who is wondering about clinical trial support, how it works, whether she will receive any.

NERVOUS

Instructions:



Read the Underlined text.



The *italicized* text are suggestions for continuing the conversation.

CHW



Clinical trials sometimes are able to offer support to the patients participating for things like transportation or compensation for lost time at work.

Client



What if they don't offer me enough money? I might not be able to participate if I can't afford it.

CHW



What should you talk about to educate your client on the available options?

Client



Anything that the CHW says to try to ease your concerns is not going to be successful. Continue to be apprehensive. Start to be convinced only if the CHW mentions alternative means of support (from the community).

Some things you should say during the conversation:



I don't know if it's a good idea for me to do a clinical trial, it sounds really risky.

I'm afraid that I'll have negative reactions to the medicine.

I'm afraid of how the trial will disrupt my life.

CHW



Conclude the conversation

SESSION 3A:

CHW roleplays explaining clinical trial support to a client

A CHW is meeting with a client who is wondering about clinical trial support, how it works, whether she will receive any.

INDIFFERENT

Instructions:



Read the Underlined text.



The *italicized* text are suggestions for continuing the conversation.

CHW



Clinical trials sometimes are able to offer support to the patients participating for things like transportation. This support can allow patients to participate when they otherwise wouldn't be able to.

Client



How do I know that the support would cover all of my costs, though? And what am I supposed to do if they don't help?

CHW



How should you respond in a way that will inform your client of her options without making her feel like you're pressuring her?

Client



You don't really care one way or the other. You're very apathetic about lupus clinical trials. Talk about how support from the clinical trial wouldn't necessarily be enough to convince you to participate.

Some things you should say during the conversation:



Can they pay for everything, like transportation and lost time at work? Because if they can't then it's not worth it.

I don't really care if they do provide support, I'm not really interested.

CHW



Conclude the conversation

ROLEPLAY THREE-B HANDOUT

SESSION 3B: CHW reaches out to a clinical trial PI

A CHW is meeting with/speaking with a clinical trial Principal Investigator (PI) to discuss barriers specific to the neighborhood. The CHW hopes that the PI will be able to take these needs into account when setting up support for the trial.

Helpful PI

Instructions:



Read the Underlined text.



The *italicized* text are suggestions for continuing the conversation.

CHW



Thank you for speaking with me about clinical trials. I know that sometimes people want to participate but are unable to because of money or logistical problems. I thought it would be useful if we talked about the types of issues people face in this neighborhood.

PI



Yes, I agree. If we can find a way to tailor the support from the clinical trial to the needs of the community, that would be great.

CHW



How would you respond to this?

PI



Show enthusiasm for the work that the CHW is doing to support the community.

Some things you should say during the conversation:



I think the two of us working together would be a huge benefit to the people in the community and to the trial I'm running.

CHW



Conclude the conversation

SESSION 3B:

CHW reaches out to a clinical trial PI

A CHW is meeting with/speaking with a clinical trial Principal Investigator (PI) to discuss barriers specific to the neighborhood. The CHW hopes that the PI will be able to take these needs into account when setting up support for the trial.

Less helpful PI/ Too busy

Instructions:



Read the Underlined text.



The *italicized* text are suggestions for continuing the conversation.

CHW



Thank you for speaking with me about clinical trials. I know that sometimes people want to participate but are unable to because of money or logistical problems. I thought it would be useful if we talked about the types of issues people face in this neighborhood.

PI



Well my clinical trial has already set the assistance figures.

CHW



How can you respond and educate?

PI



There are two ways that you could play this. You are either completely uninterested in helping the CHW or you are interested but unable to help for the specific trial you are currently working on.

Some things you should say during the conversation:



Uninterested: I'm very busy, and I don't really have the time to do anything for you.

Uninterested: I don't really care what the specific needs of the community are.

Interested but not right now: I think future collaborations might be helpful, but I can't do anything for the trial I'm currently running.

Interested but not right now: I might know some other PIs in the area that I could connect you with.

CHW



Conclude the conversation

ROLEPLAY FOUR HANDOUT

SESSION 4:

CHW helping a client
fill out paperwork for
clinical trial enrollment

A client has decided to enroll in a clinical trial and the CHW has offered to help her fill out the paperwork.

ARGUMENTATIVE

Instructions:



Read the Underlined text.



The *italicized* text are suggestions for continuing the conversation.

CHW



I know there's a lot of paperwork for you to fill out for your trial, so I thought I could help guide you through it.

Client



Why do I have to fill all this stuff out? Can't they just get this info from my doctor? If it takes me so long to do this, why should I do the trial at all?

CHW



Respond in a way that will best help your client

Client



You should be very displeased with all of the paperwork that you have to fill out. No matter what the CHW says, you are not convinced that it's necessary or that you should have to do it.

CHW



Explain why the trial is collecting her information and why it's important.

Client



Some things you should say during the conversation:



Why do they need to know all the stuff they're asking me?

If they're asking for all of this information, I bet they're going to use it against me.

CHW



Conclude the conversation

SESSION 4:

CHW helping a client
fill out paperwork for
clinical trial enrollment

A client has decided to enroll in a clinical trial and the CHW has offered to help her fill out the paperwork.

POSITIVE

Instructions:

Read the Underlined text.



The *italicized* text are suggestions for continuing the conversation.

CHW



I thought it would be helpful for you if we started to fill out your clinical trial paperwork together.

Client



Yes, I can see that there's a lot to fill out! I think it's great that they are being so thorough documenting everything. It makes me feel safer participating.

CHW



Respond in a way that will best help your client.

Client



Maintain a positive personality. Talk about how it inspires confidence in the researchers running the trial.

CHW



Explain why the trial is collecting her information and why it's important

Client



Some things you should say during the conversation:



If they're taking such care to document everything like this, then I think this means that nothing could go wrong with the trial.

But do they really need to ask all this? It makes me feel safer, but what do they do with all this information?

CHW



Conclude the conversation

SESSION 4:

CHW helping a client
fill out paperwork for
clinical trial enrollment

A client has decided to enroll in a clinical trial and the CHW has offered to help her fill out the paperwork.

NERVOUS**Instructions:**

Read the **Underlined** text.



The ***italicized*** text are suggestions for continuing the conversation.

CHW



I know there's a lot of paperwork for your trial, so I thought it would be helpful for you if we started to fill it out together.

Client



I don't understand why there's so many papers to fill out. What are they making me promise to do? Am I signing away my rights?

CHW



Respond in a way that will best help your client.

Client



The CHW will not be able to make you less nervous. Continue to be apprehensive and nervous about clinical trials.

CHW



Explain why the trial is collecting her information and why it's important

Client



Some things you should say during the conversation:



A lot of this stuff sounds so complicated. I don't like that I can't understand everything it says.

Why is there so much to do? Why do they need to know all this information? Are they going to use it against me?

CHW



Conclude the conversation

SESSION 4:

CHW helping a client
fill out paperwork for
clinical trial enrollment

A client has decided to enroll in a clinical trial and the CHW has offered to help her fill out the paperwork.

INDIFFERENT

Instructions:



Read the Underlined text.



The *italicized* text are suggestions for continuing the conversation.

CHW



I thought it would be helpful for you if we started to fill out your clinical trial paperwork together.

Client



I just don't understand why I have to do this. What's the point?

CHW



Respond in a way that will best help your client.

Client



You don't really care one way or the other. You're very apathetic and wondering why you have to fill out so much info.

CHW



Explain why the trial is collecting her information and why it's important.

Client



Some things you should say during the conversation:



How does filling out all this paperwork help me? Are they trying to trick me with some of this?

Do I really have to do every single page of this?

CHW



Conclude the conversation

ELEVATOR SPEECH HANDOUT

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Below are several topics that you should try to incorporate into your elevator speeches.

- ① Open the conversation of clinical trials in a friendly and approachable manner

- ② Explain the definition of a clinical trial

- ③ Explain the protocols associated with a clinical trial

- ④ Explain why clinical trials are important

- ⑤ Talk about the potential benefits from participating in a clinical trial

